NIAMS CLINICAL TRIAL OUTCOMES INSTRUMENT DEVELOPMENT GRANT PROGRAM

RELEASE DATE: October 27, 2003

RFA Number: RFA-AR-04-005

Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATIONS:
National Institutes of Health (NIH)
(http://www.nih.gov)

COMPONENTS OF PARTICIPATING ORGANIZATIONS:
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
(http://www.niams.nih.gov/)

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER (S): 93.846

LETTER OF INTENT RECEIPT DATE: December 13, 2003
APPLICATION RECEIPT DATE: January 13, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS RFA

This announcement solicits research applications to develop, apply and evaluate new clinical trial outcomes measures of safety, efficacy and effectiveness of therapies for diseases, illnesses and injuries of interest to the NIAMS. Clinical trials in rheumatic, skin, bone and muscle diseases are often hampered by the lack of validated outcome measures or by outcome measures that are cumbersome, time-consuming and costly. Increasing

availability of computer modeling and statistical approaches, along with better understanding of disease natural history, have yielded new concepts and new models that may be relevant to the development of new and refined outcomes for clinical trials in diseases, illnesses and injuries of interest to the NIAMS. This RFA is intended to accelerate the development and testing of new outcomes measures and instruments that could lead to improved trial designs or to the development of consensus about new instruments based on new or existing measures.

RESEARCH OBJECTIVES

Background

The ability to conduct well-designed clinical studies to assess efficacy of new therapies depends on the identification of clinically relevant endpoints and development of sensitive and specific instruments that accurately reflect the course and stage of disease. Except for the most common diseases (i.e., rheumatoid arthritis, osteoporosis), outcomes measures and benchmarks for comparison of clinical outcomes are sorely lacking in most areas of clinical research interest to NIAMS. For some diseases, a number of outcome instruments exist but they are not used consistently. For example, in lupus, there are more than 20 “instruments” that can be used in clinical trials to measure outcomes. Some measure disease activity, some measure organ damage, some are composite or index instruments that capture some, but not all, components/responses in disease. Often, lupus clinical trials are conducted using similar therapeutics but different outcomes instruments. This makes the comparison of results and the potential efficacy, toxicity, and complications of new therapeutic approaches very difficult. In addition, it hampers efforts by organizations, such as the FDA, to develop guidance documents for industry with benchmarks for approval of new agents. The same applies to many other diseases, illnesses and injuries of interest to the NIAMS.

In spite of the diversity of potential therapeutic approaches, trials in diseases, illnesses and injuries of interest to the NIAMS are difficult because many of the diseases are rare; the clinical manifestations are heterogeneous, requiring long-term follow-up; and the outcomes are often measured with "disease index/activity" measure instruments, which are a combination of many clinical parameters. The lack of proven therapies for other diseases of interest to the NIAMS such as muscular dystrophy, inflammatory myopathies, and other muscle and skin diseases is due in part to the rarity and heterogeneity of these diseases and in part to the lack of standardized and validated approaches for assessing disease activity and damage in patients. Skeletal muscle specific outcome measures or validated surrogate markers are not adequate for studies of treatments or systematic longitudinal assessments. Common, chronic diseases such as lupus, rheumatoid arthritis or osteoarthritis, require long term follow up, and there may be no consensus about the best outcomes measures for trials aimed at structural change (i.e., prevention of erosion, delayed joint space narrowing, etc), single organ damage prevention (i.e., lung fibrosis in scleroderma), or surgical treatments. These factors contribute to clinical trial designs that frequently involve a large number of patients and are very costly. In a recent NIAMS-sponsored lupus conference, the private sector identified the lack of understandable,

universal outcomes measures as the primary impediment to embarking more vigorously in clinical trials for this disease. (http://www.niams.nih.gov/ne/reports/sci_wrk/2002/summary.htm).

In addition to established therapies, new agents and approaches are being developed in laboratories and tested in experimental animals for repair/replacement and preventive interventions of diseases, illnesses and injuries of interest to the NIAMS. Trials for these agents/technologies are also difficult because the primary outcome measure may be distant to the therapeutic target. For example, the prevention of lupus nephritis with a tolerogenic dose of a very specific agent is difficult to evaluate when the outcome is changes in a disease activity index that combines indicators of many organ systems and overall disease activity.

New technologies are being applied rapidly to the development of biomarkers of disease for identification of patient subsets, evaluation of disease outcomes, evaluation of response to therapies and the identification of predictors of outcomes. However, it is unclear how these potentially valuable biomarkers (i.e., array data) can be incorporated into disease outcome measure instruments in a meaningful way. Thus, there is a great need to refine existing instruments to incorporate biomarkers and to test biomarkers together with other outcomes in large cohorts. New techniques in the areas of clinimetrics, statistical analysis, computer simulation, etc. may help improve the design of relevant outcome variables that include biomarkers to be used in smaller, more cost-effective trials.

Scope

This RFA encourages projects that propose to design, evaluate, validate, and test new and/or improved outcome measures for clinical trials in diseases, illnesses and injuries of interest to the NIAMS (see http://www.niams.nih.gov/rtac/funding/faq.htm). The experimental design of a project may include, for example, consensus development approaches, meetings of experts, collection of data, beta testing of new instruments, mathematical and computer modeling, validation studies. The proposal should include plans to disseminate information and have input from relevant scientific communities and professional organizations on the scientific merit and applicability of new and improved outcomes. Approaches that take advantage of bioinformatics to speed up data collection, analysis, dissemination and updates are encouraged.

Suggested topics may include, but are not limited to:

o The use of the preliminary definitions of improvement for adult and juvenile disease as primary or secondary endpoints.

o New outcomes to evaluate disease damage and their interaction/combination with other disease outcomes.

o New outcomes (i.e., biomarkers, imaging modalities) to functionally assess the early progress/success of interventions such as tissue-engineered repairs.

o Outcomes tools that includes biomarkers, new imaging and other technologies in the evaluation of responses to diagnostic procedures and non-operative and operative treatments.

o Uses of health-related quality of life measures in the context of chronic rheumatic, musculoskeletal, muscle and skin diseases, illnesses and injuries in adult and pediatric patients.

o Development of new methods for collection of a common core set of measures that could be used in different trials that would ensure more uniform reporting of outcome measures.

o Approaches that allow the combination of the data from trials in which all measures have been collected to confirm the validity of the preliminary definition of improvement (DOI) and attempt to derive improved DOIs.

o Approaches to facilitate the updating, sharing and disseminating of trial data, current core set measure forms, and uniform data collection procedures.

o Identification, access and use of existing databases to analyze and test new or combined outcomes measures.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) R01 (investigator-initiated research project grant). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Before making an award for an investigator-initiated clinical trial outcomes instrument development project, the NIAMS will consider the desirability of substantial continued staff involvement in an assistance mode. If such involvement is deemed appropriate by the Institute, the award mechanism will be a cooperative agreement. Regardless of the mechanism of support, NIAMS staff will closely monitor progress during the award. This monitoring may include regular communications with the principal investigator and staff, the request to develop mutually agreeable milestones for the work to be done, and attendance at the steering committee and other project-related meetings. The Terms and Conditions for an award will include milestones expected to be met by projects at specific time periods, any requirements regarding minimum effort of specific investigators, and any other identified requirements for completion of the approved research. As with any award, continuation, even during the period recommended for support, is conditional upon satisfactory progress. Applicants may request up to $150,000 (direct costs) per year for up to three years. These awards are not renewable.

This RFA uses just-in-time concepts. It also uses the modular budgeting format. (See http://grants.nih.gov/grants/funding/modular/modular.htm). Specifically, if you are submitting an application with direct costs in each year of $250,000 or less, use the modular budget format. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm.

Specifically, when an application is submitted with direct costs in each year of $250,000 or less, the modular format should be used. The anticipated award date is December 2004. Applications that are not funded in the competition described in this RFA may be resubmitted as NEW investigator-initiated applications using the standard receipt dates for NEW applications described in the instructions to the PHS 398 application. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm.

FUNDS AVAILABLE

The NIAMS intends to commit approximately $1.0 million in FY 2004 to fund four or five new grants in response to this RFA. An applicant may request a project period of up to three years and a budget for direct costs of up to $150,000 per year. Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the NIAMS provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

o For-profit or non-profit organizations
o Public or private institutions, such as universities, colleges, hospitals, and laboratories
o Units of State and local governments
o Eligible agencies of the Federal government
o Faith-based or community–based organizations
o Domestic or foreign institutions/organizations

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Susana Serrate-Sztein, M.D.
Director, Genetics and Clinical Studies Program, NIAMS, NIH
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-5032
FAX: (301) 480-4543
Email: szteins@mail.nih.gov

Alan Moshell, M.D.
Director, Skin Diseases Program, NIAMS, NIH
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-5017
FAX: (301) 480-4543
Email: moshella@mail.nih.gov

Joan McGowan, Ph.D.
Director, Bone Diseases Program, NIAMS, NIH
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: mcgowanj@mail.nih.gov

James S. Panagis, M.D.
Director, Orthopaedics Program, NIAMS, NIH
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: panagisj@mail.nih.gov

Gayle E. Lester, Ph.D.
Program Director, Osteoarthritis Initiative & Diagnostic Imaging, NIAMS, NIH

One Democracy Plaza
6701 Democracy Boulevard Suite 800, MSC 4872
Bethesda, Maryland 20892-4872
Telephone: (301) 594-3511
FAX: (301) 480-4543
Email: lester1@mail.nih.gov

o Direct your questions about peer review issues to:

Teresa Nesbitt, D.V.M., Ph.D.
Chief, Review Branch, NIAMS, NIH
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-5032
Telephone: (301) 594-4953
FAX: (301) 480-4543
Email: nesbittt@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Mr. Michael G. Morse
Deputy Chief, Grants Management Branch, NIAMS, NIH
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: morsem@mail.nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research
o Name, address, and telephone number of the Principal Investigator
o Names of other key personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to:

Susana Serrate-Sztein, M.D.
Director, Genetics and Clinical Studies Program, NIAMS, NIH
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-4872
Telephone: (301) 594-5032
FAX: (301) 480-4543
Email: szteins@mail.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at http://www.dunandbradstreet.com/. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo,
Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS:
Applications requesting up to $250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in $25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at http://grants.nih.gov/grants/funding/modular/modular.htm.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/labels.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original

of the application, including the Checklist and three signed photocopies, in one package to:

Center For Scientific Review
National Institutes Of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Teresa Nesbitt, D.V.M., Ph.D.
Chief, Review Branch
NIAMS
One Democracy Plaza
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20872-5032
Telephone: (301) 594-4953
FAX: (301) 480-4543
Email: nesbittt@mail.nih.gov

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is, the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness and responsiveness by the CSR and the NIAMS. Incomplete and/or nonresponsive applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
o Receive a written critique
o Receive a second level review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

o Significance
o Approach
o Innovation
o Investigator
o Environment

The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

SIGNIFICANCE: Does this study address an important problem? If the aims of the application are achieved, how will clinical trials be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

INNOVATION: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

INVESTIGATOR: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL REVIEW CONSIDERATIONS

SHARING RESEARCH DATA: The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: December 13, 2003
Application Receipt Date: January 13, 2004
Peer Review Date: July 2004
Council Review: December 2004
Earliest Anticipated Start Date: December 2004

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o Scientific merit (as determined by peer review)
o Availability of funds
o Programmatic priorities.

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA

Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to Volume Index

Return to NIH Guide Main Index
